JAN 3 0 2002

510(k) SUMMARY

K013617 1/2

LTF-240 Pleuravideoscope, its accessories and ancillary equipment

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section807.92.

A. Submitter's Name, Address, Phone and Fax Number

1. Manufacturer of the subject device

Name & Address of Manufacturer;	Olympus Optical Co,. Ltd. 2-3-1 Shinjuku Monolis Nishi-shinjuku Shinjuku-ku, Tokyo, 163-0914 Japan
Registration No :	810047
Address, Phone and Fax Number of R&D Department Endoscope Division	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-5177 FAX 81-426-46-5613

2 Name of Contact Person

Name :	Ms.Laura Storms-Tyler Director, Regulatory Affairs Olympus America Inc.
Address, Phone and Fax	Olympus America Inc. Two Corporate Center Drive Melville, NY 11747-3157 TEL (631)844-5688 FAX (631) 844-5416

B. Device Name, Common Name

1. Device Name :	LTF-240 Pleuravideoscope, its accessories and ancillary equipment
2. Common/Usual Name :	Video Scope for Pleuravideoscope
3. Classification Name :	21CFR 884.1720 21CFR 876.1500

C. Predicate Devices:

Model	Device Description & 410(k)#/Date of Cleared	Manufacturer	Class
OES Laparo-Thoracoscope LTF-V	#K955403	Olympus Optical Co.,	II
Laparoscope, Hand Instruments	#K950103	Olympus America, Inc.	II
Flexible Trocar Tubes	#K930215	Olympus Optical Co.,	II
Flexible Tip Thoracoscope/Laparoscope	#K915857	Olympus Optical Co.,	

D. Summary Description of the Device

1. Summary

This subject device "XENF-DP Rhino-Laryngofiberscope" is the endoscope for observation within nasal and nasopharyngeal lumen. This endoscope enables two ways of light source, detachable and single use battery powered and light cable source.

2. Design

"XENF-DP Rhino-Laryngofiberscope" has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirements of IEC 60601-1 and IEC60601-2-18.

3. Materials

There are no new patient-contacting materials. All of patient contact materials are cleared by previous 510(k) submissions.

E. Intended Use of the device

This instrument has been designed to be used with an Olympus Light Source or an Olympus Miniature Light Source, documentation equipment, display monitor, and other ancillary equipment of endoscopic diagnosis with the nasal and nasopharyngeal lumen.

F. Technological Characteristics

This endoscope does not have special technological characteristics, when compared to the predicate device.

G. Reason for not requiring clinical data

The subject device, LTF-240, is basically identical to the LTF-V laparoscopic thoracoscope, which is a flexible endoscope indicated for use in the thoracic and abdominal cavities, with the exception being that the LTF-V is not indicated for electrosurgery applications.

Historically, electrosurgery within the thoracic and abdominal cavities has been performed using a rigid endoscope. The use of the subject device, which is a flexible endoscope, should present no differences in safety or efficacy when compared to the predicate devices for electrosurgical applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2002

Olympus Optical Company, Ltd.
c/o Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
Two Corporate Center Drive
Melville, New York 11747

Re: K013617
Trade/Device Name: LTF-240 Pleuravideoscope, accessories and ancillary equipment
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: November 1, 2001
Received: November 5, 2001

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OLYMPUS

Indication for Use Statement

510(k) Number(if known): K013617 Not assigned yet.

Device Name: LTF-240 Pleuravideoscope, its accessories and ancillary equipment.

Indications for Use:

This instrument has been designed to be used with an OLYMPUS video system center, light source, documentation equipment, video monitor, endo-therapy accessories(such as a biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013617

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Prescription 21 CFR 801.109)

(Optional Format 1-2-96)